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Regulatory  
Town Hall

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## Notice of Intended Regulatory Action (NOIRA) Agency Background Document

<b>Agency name</b>	Department of General Services, Division of Consolidated Laboratory Services
<b>Virginia Administrative Code (VAC) citation</b>	1VAC30-46
<b>Regulation title</b>	Accreditation for Commercial Environmental Laboratories
<b>Action title</b>	Revise regulation to meet 2009 TNI Standards and to update procedural and fee requirements
<b>Date this document prepared</b>	December 7, 2011

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

### Purpose

*Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.*

1VAC30-46 sets out the requirements to accredit commercial laboratories that analyze environmental samples used to determine compliance with the State Water Control Law, Virginia Waste Management Act, and the Virginia Air Pollution Control Law. 1VAC30-46 uses the NELAC Institute (TNI) standards to accredit commercial environmental laboratories. The TNI standards are revised every few years.

The proposed action will replace the current 2003 standards used to accredit laboratories with the 2009 TNI standards. Commercial environmental laboratories need to meet these standards in order to remain accredited under the nationally-accepted TNI program.

The proposed action will eliminate all the requirements related to the initial accreditation period. These changes mainly affect the application procedures. The process to renew accreditation will be streamlined, reducing the cost for both the agency and the accredited laboratories.

The proposed action will revise the fees charged to laboratories under the program. The current fees are insufficient to support the program because fewer laboratories applied for accreditation than originally anticipated.

## Legal basis

*Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.*

### Virginia Legal Authority

Section 2.2-1102 A 1 of the *Code of Virginia* authorizes the Department of General Services (DGS) to prescribe regulations necessary or incidental to the performance of the Department's duties or execution of powers conferred by the *Code*.

Section 2.2-1105 A of the *Code of Virginia* authorizes the Division of Consolidated Laboratory Services (DCLS) to establish and conduct a program for the certification of laboratories conducting any tests, analyses, measurements, or monitoring required pursuant to Chapter 13 (§ [10.1-1300](#) et seq.) of Title 10.1 [Air Pollution Control Law], the Virginia Waste Management Act (§ [10.1-1400](#) et seq.), or the State Water Control Law (§ [62.1-44.2](#) et seq.). Section 2.2-1105 C of the *Code of Virginia* authorizes DCLS establish a fee system to pay for the costs of the certification program.

### Promulgating Entity

The promulgating entity for this regulation is the Division of Consolidated Laboratory Services of the Department of General Services.

## Need

*Please detail the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, delineate any potential issues that may need to be addressed as the regulation is developed.*

Environmental laboratories are required by §2.2-1105 of the *Code of Virginia* to be accredited before submitting data to the Department of Environmental Quality under Virginia's air, water, and waste laws and regulations. This statutory requirement is carried out by DCLS under the regulatory requirements of 1VAC30-45 (noncommercial laboratories) and 1VAC30-46 (commercial laboratories).

DCLS accredits the commercial laboratories (1VAC30-46) using the national environmental laboratory accreditation standards developed by the NELAC Institute (TNI). DCLS currently accredits commercial environmental laboratories to the 2003 standards. TNI has replaced the 2003 standards with the 2009 standards. The commercial environmental laboratories need to meet these 2009 revised standards in order to remain accredited under TNI. DCLS must incorporate the 2009 standards into 1VAC30-46 in order to continue to accredit laboratories

under the TNI program. The TNI program standards are the only available national standards for the accreditation of environmental laboratories. TNI revises their standards to improve those standards and to provide the most up-to-date information available for the accreditation of environmental laboratories.

Accrediting commercial environmental laboratories to a single set of standards has several benefits. Environmental laboratories test environmental samples to determine whether the samples meet the air and water pollutant and waste limits set by DEQ. Under the accreditation program, all environmental laboratories meet the same proficiency testing and quality assurance and quality control standards. Meeting these standards ensures that the laboratories are providing results of known quality and defensibility for measurements of pollutants in environmental samples. The limits set by DEQ for air, water and waste pollutants protect public health and welfare. Laboratory measurements of environmental samples determine compliance with Virginia's environmental laws and therefore are the key to providing protection of public health and welfare.

Revising 1VAC30-46 to streamline the application and accreditation renewal process reduces the administrative requirements for laboratories and for DCLS.

When DCLS developed the accreditation program under §2.2-1105, the agency estimated but did not know how many laboratories would need to apply to be accredited. The initial accreditation period is over and the agency now knows the number of laboratories covered by the program. The number of laboratories covered by the program was overestimated. The fees charged by the program as a result are too low. DCLS needs to adjust the fees to cover the cost of the program as required by §2.2-1105 C.

**Substance**

*Please detail any changes that will be proposed. Be sure to define all acronyms. For new regulations, include a summary of the proposed regulatory action. Where provisions of an existing regulation are being amended, explain how the existing regulation will be changed.*

The following revisions to 1VAC30-46 are being considered:

1. Revise Part II of 1VAC30-46 to incorporate by reference the 2009 TNI standards, deleting the 2003 NELAC standards. Revise the definitions in 1VAC30-46-40 to meet the definitions in the 2009 TNI standards.
2. Revise Part I of 1VAC 30-46 to indicate when commercial environmental laboratories will need to meet the 2009 standards.
3. Revise Part I of 1VAC30-46 to eliminate the requirements for the initial accreditation period.
4. Revise Part I of 1VAC30-46 to simplify the renewal procedural to reduce the burden on laboratories and the agency.
5. Revise the fee provisions of 1VAC30-46-150 so that the fees cover the costs of the program.

## Alternatives

*Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action. Also, please describe the process by which the agency has considered or will consider other alternatives for achieving the need in the most cost-effective manner.*

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DCLS could choose to continue accrediting commercial environmental laboratories to the 2003 NELAC standards instead of revising 1VAC30-46 to incorporate the 2009 TNI standards. The agency believes this would not be a good alternative. The commercial environmental laboratories would lose their national standing as TNI-accredited laboratories. These laboratories as a result would not be able to acquire efficient accreditation in other states offering TNI accreditation. The laboratories will benefit from the 2009 standards. The 2009 standards are better organized than the 2003 standards and provide more flexibility for the laboratories to become accredited and to maintain their accreditation status.

DCLS could choose to keep the fees at their current levels. However §2.2-1105 C requires the program to charge fees sufficient to cover the accreditation program. Fewer laboratories than anticipated at the inception of the program have applied for accreditation. The fees need to be increased as a result. The agency believes there is no alternative to increasing the fees given the statutory requirement as well as the budgetary need for fee support of the program.

DCLS could choose to retain the procedural requirements that pertain to the initial accreditation period. DCLS believes these requirements are now extraneous to the regulation and no longer necessary.

DCLS could choose to retain the accreditation renewal requirements. DCLS believes however that these requirements are cumbersome. The laboratories and DCLS would be better served by a streamlined process.

## Public participation

*Please indicate whether the agency is seeking comments on the intended regulatory action, including ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public hearing is to be held to receive comments on this notice.*

*Please also indicate, to the extent known, if standing or ad hoc advisory panels (also known as regulatory advisory panels) will be involved in the development of the proposed regulation. Indicate whether 1) the agency is not using the participatory approach in the development of the proposal because the agency has authorized proceeding without using the participatory approach; 2) the agency is using the participatory approach in the development of the proposal; or 3) the agency is inviting comment on whether to use the participatory approach to assist the agency in the development of a proposal.*

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The agency is seeking comments on this regulatory action, including but not limited to 1) ideas to be considered in the development of this proposal, 2) the costs and benefits of the alternatives stated in this background document or other alternatives and 3) potential impacts of the regulation. The agency is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) the probable effect of the regulation on affected small businesses, and 3) the description of less intrusive or costly alternatives for achieving the purpose of the regulation.

Anyone wishing to submit comments may do so via the Regulatory Town Hall website (<http://www.townhall.virginia.gov>), or by mail, email, or fax to Nancy S. Saylor, in c/o DCLS, 600 North 5th Street, Richmond, VA, 23219, [nssaylor@verizon.net](mailto:nssaylor@verizon.net), 804-231-7980 (phone) or 804-371-7973 (fax). Written comments must include the name and address of the commenter. In order to be considered, comments must be received by midnight on the last day of the public comment period.

A public hearing will not be held following the publication of the proposed stage of this regulatory action.

### Family impact

*Assess the potential impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.*

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It is not anticipated that the proposal will have a direct impact on families. There will be a positive indirect impact on families in that the proposal will protect public health and welfare.